

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q97391

Akio SUGIHARA, et al.

Appln. No.: 10/594,127

Group Art Unit: 1625

Confirmation No.: 8975

Examiner: Niloofar RAHMANI

Filed: September 25, 2006

For: COMPOSITION OF SOLIFENACIN OR SALT THEREOF FOR USE IN SOLID FORMULATION

**PETITION TO WITHDRAW FINALITY**

**MAIL STOP AMENDMENT**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

Applicant submits that the final Office Action dated August 25, 2009, improperly has been made final and thus respectfully solicits withdrawal of the finality of the Office Action.

Specifically, claims 10, 12 and 17 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner states that claims 10, 12 and 17 are drawn to pharmaceutical composition of solifenacin or a salt thereof for use in a solid formulation, the composition containing crystalline and amorphous solifenacin or a crystalline and amorphous salt thereof, together with an inhibitor of an amorphous preparation, wherein the inhibitor of an amorphous preparation is a substance having an ethylene oxide chain and wherein the crystalline and amorphous solifenacin or a crystalline and amorphous salt

thereof is not in contact with or in mixture with the inhibitor of an amorphous preparation, which has no antecedent basis in the specification.

However, the Examiner did not specifically indicate why the passage from the specification provided in the Response filed June 16, 2009, is not sufficient to provide support for amended claim 10. For at least this reason, the Action is improper. MPEP § 707.07(f) requires the Examiner to provide clear explanations of all actions taken during the prosecution of the application in order to provide a complete prosecution history and to enhance clarity of the prosecution history record. Further, the Examiner should respond specifically to traversals. (“Where the applicant traverses any rejection, the examiner, should, if he or she repeats the rejection, take note of the applicant’s argument and answer the substance of it.”).

Additionally, it is improper to make the first Action after a RCE final where the Examiner previously refused to enter proposed claim amendments based on the assertion that the proposed amendment presented new matter. See MPEP § 706.07(b). In view of the Examiner’s position, applicants filed an RCE and amended the claim language. Although the language in the present claims is slightly different from that in the Amendment filed April 16, 2009, which was not entered by the Examiner allegedly because the proposed amendment raised issues of new matter, the language is similar and the issue is the same.

Moreover, the Examiner states that “*if* the new matter is removed from claim 10 the following rejections will be maintained:

- (1) the rejection of claims 10, 12 and 17 under 35 U.S.C. §102(e) over Slatter et al., US 2004/0138253;

(2) the rejection of claims 10, 12 and 17 under 35 U.S.C. §102(e) over Fraser et al.,  
US 2004/0198822;

(3) the rejection of claims 10, 12 and 17 under 35 U.S.C. §102(e) over Saito et al., US  
2005/0181031; and

(4) the rejection of claims 10, 12 and 17 under 35 U.S.C. §102(e) over Fraser et al.,  
US 2005/0239890.

This is also improper because the Examiner fails to address the claims as amended. MPEP §2163.06(I) clearly states that even when a new matter rejection is made, the Examiner should still consider the subject matter added to the claim in making rejections based on prior art since the new matter rejection may be overcome by Applicant.

For the reasons discussed above, Applicant requests that the finality of the Office Action be withdrawn and a new Non-Final Office Action with a new time period for reply should be issued addressing the claims as amended and providing a clear explanation as to why the disclosure in the specification is not considered sufficient to provide support for amended claim 10.

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The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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